UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,208	11/12/2003	Carol Ann Morris	CL/V-32765A	5997

31781 7590 11/29/2006

CIBA VISION CORPORATION
PATENT DEPARTMENT
11460 JOHNS CREEK PARKWAY
DULUTH, GA 30097-1556

EXAMINER	
WOOD, AMANDA P	

ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,208	MORRIS ET AL.	
	Examiner	Art Unit	
	Amanda P. Wood	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 September 2006 has been entered.

Claims 1-6 are presented for consideration on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Third Party Submission

A third-party submission has been filed under 37 CFR 1.99 on 30 June 2006 in the published application. The document cited in the third-party submission is US Patent 6,544,193.

To ensure that a third-party submission does not amount to a protest or pre-grant opposition, 37 CFR 1.99 does not permit the third party to have the right to insist that the examiner consider any of the patents or publications submitted. Furthermore, if the submission or part of the submission is not in compliance with 37 CFR 1.99, that noncompliant submission or part thereof will not be entered in the application file.

Therefore, unless the examiner clearly cites a patent or publication on form PTO-892, Notice of References Cited and such reference is used in a rejection or its relevance is actually discussed during prosecution, consideration by the examiner of any patent or publication submitted in a third-party submission cannot be presumed.

If the applicant wants to ensure that the information in a third-party submission is considered by the examiner, the applicant should submit the information in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98. An individual who has a duty to disclose under 37 CFR 1.56 should also submit any material information contained in a third-party submission to the Office in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98 to ensure such material information is properly disclosed to the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, claim 1 is drawn to a method comprising the steps of contacting a glucose-sensing ophthalmic device with an ocular fluid of a patient without fasting. The

particular limitation of "contacting a glucose-sensing ophthalmic device with an ocular fluid" was not described by Applicant in the instant specification in such a way that one of ordinary skill in the art to which it pertains would be able to practice the instantly claimed invention without an undue amount of experimentation. Applicant specifies at paragraph [0054] of the pre-grant publication for the instant specification that a glucose-sensing ophthalmic device may be a soft or hard contact lens, an intraocular lens, a corneal overlay, or ophthalmic devices such as stents or implants. Furthermore, Applicant describes methods of assaying tears on tear collecting devices such as a soft hydrogel strip, and gives a specific example of collecting tears from patients using a microcapillary tube and then measuring the glucose concentration in the collected tears. However, Applicant does not give any examples of or even describe any method wherein a glucose-sensing ophthalmic device is contacted with an ocular fluid of a patient. Furthermore, Applicant does not provide any examples in the instant specification wherein the tear glucose of patients without fasting was tested. The lone example offered by Applicant describes fasting patients' tear glucose levels before and after oral carbohydrate loads were given and that a diabetic patient's tear glucose after the oral carbohydrate compared to that before the oral carbohydrate is at least about 1.5 folds larger (shown in Figure 1). Applicant does not provide any examples of tear glucose levels in patients without fasting that would indicate that the ratio for levels after carbohydrate administration compared to before would also be at least 1.5 or larger in diabetics. Therefore, it would take an undue amount of experimentation, based upon

the lack of guidance provided by Applicant with respect to the limitations described above, for one of ordinary skill in the art to practice the claimed invention.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over March (US 6,681,127) in view of Chen et al (J. Cap. Elec. 1996) and the American Diabetes Association (2002).

A method for rapidly screening for diabetes is claimed, wherein a glucose-sensing ophthalmic device is contacted with ocular fluid of a patient without fasting, a first glucose concentration is obtained, a carbohydrate load is administered, a second glucose concentration is obtained, and the first and second glucose concentrations are compared to determine if a patient is diabetic.

March teaches a method of testing the concentration of an analyte (I.e., glucose) in ocular fluid (i.e., tears) wherein a glucose-sensing ophthalmic lens (i.e., device) is contacted with ocular fluid to determine the glucose concentration. March further teaches that the glucose-sensing ophthalmic lens testing agent composition comprises a receptor moiety with a binding site for the glucose and a competitor moiety wherein binding of the glucose or the competitor to the receptor binding site is reversible, wherein the amount of detectably labeled competitor that is displaced from the receptor by the glucose provides a means of determining the glucose concentration. March

teaches that the competitor moiety comprises a detectable label, such as a fluorescent label, and that it is most preferable that the detectable fluorescent label be more readily detectable when the competitor is not bound to the analyte/competitor binding site of the receptor. Therefore, when the fluorescently labeled competitor is not bound to the receptor binding site, (i.e., displaced by the analyte glucose) the fluorescence is unquenched, and when the competitor is bound to the receptor (i.e., not displaced by glucose) the fluorescence is quenched (see, for example, Abstract, col. 3, lines 10-55 and col. 4, lines 1-40, and col. 10, lines 30-45).

March does not expressly teach a method wherein the ocular fluid of a patient without fasting is tested at a period of time less than 50 minutes after orally administering a load of carbohydrate.

Chen et al beneficially teach a method wherein tear glucose in a non-fasting subject is determined with a first tear glucose level before the subject's regular three meals (which can consist of a carbohydrate load) and a second tear glucose level 30 minutes (i.e., less than 50 minutes after orally administering a carbohydrate load) after each meal (i.e., tear glucose levels before the meals are non-fasting since they are taken between the subject's meals for the day). Furthermore, the first and second tear glucose levels are compared in the subject, showing a consistent 9% increase in tear glucose after each meal above the pre-meal level. Chen et al teach that the blood glucose concentrations for the same individual at the same time intervals do not follow this same pattern (see, for example, Figure 5, and page 247). Chen et al teach that the subject used for this experiment was normal, not considered diabetic. However, Chen

et al beneficially teach that determination of glucose in tears is a viable noninvasive screening method to detect diabetes mellitus and that this procedure can be used to follow glucose concentration changes in tear fluid, based upon the appearance of a direct correlation between glucose in blood and glucose in tears (see, for example, Figure 4).

March does not expressly teach a method wherein the ratio of the second tear glucose level over the first tear glucose level is at least about 1.5 or larger.

The American Diabetes Association (ADA) published a position statement in January 2002 regarding the glucose concentration levels for diagnosis of diabetes. The fasting plasma glucose level for patients found to be diabetic is greater than or equal to 126 mg/dL, and the plasma glucose level for patients found to be diabetic after the 2 hour glucose tolerance test is greater than or equal to 200 mg/dL. Patients who are found to have these glucose levels are considered to be diabetic (see, for example, pg. S22). The ratio of the second glucose concentration over the fasting glucose concentration is about 1.59 (i.e., about 1.5 or larger).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the glucose-sensing ophthalmic device of March in a method to screen for diabetes based upon the beneficial teachings provided by Chen et al, with respect to the art-recognized correlation between tear and blood glucose levels, and methods of detecting tear glucose in subjects within 30 minutes of eating. One of ordinary skill in the art would have been motivated to substitute an oral carbohydrate load for the meals taught by Chen et al for the expected benefit of

providing a consistent level of carbohydrate to be administered to subjects when screening for diabetes, as opposed to following tear glucose levels. In addition, the ADA specifically points out that the diagnosis of diabetes is based upon glucose concentrations of particular levels, and therefore one of ordinary skill in the art, with the knowledge that tear glucose correlates with blood or plasma glucose, would have been motivated and equipped to determine the ratio for diagnosis of diabetes using a glucose-sensing ophthalmic device such as that taught by March, and incorporating the teachings of Chen et al. Furthermore, both March and Chen et al particularly point out that glucose levels can be determined using tears, and therefore, it would have been both obvious and beneficial for the skilled artisan to use the methods taught by March and Chen et al to screen for diabetes so as to avoid repeated needlesticks normally encountered in screening patients for diabetes. The result-effective adjustment of particular conventional working conditions (e.g., administering a particular amount of glucose, waiting for a particular amount of time, and/or using particular detectable optical signals) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

APW

CHRISTOPHER R. TATE
PRIMARY EXAMINER